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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
06/618,570	06/08/84	RUGINI	84-19550

BUCHMAN AND ARCHER
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EXAMINER	
ABRAHAMSON, F	
ART UNIT	**PAPER NUMBER**
125	5

DATE MAILED: 05/24/85

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 5/11/85 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), ____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice re Patent Drawing, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449
4. ☐ Notice of Informal Patent Application, Form PTO-152
5. ☐ Information on How to Effect Drawing Changes, PTO-1474
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☒ Claims 1-13 are pending in the application.
   Of the above, claims 8-13 are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 1-7 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings which are acceptable for examination purposes until such time as allowable subject matter is indicated.
8. ☐ Allowable subject matter having been indicated, formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. These drawings are ☐ acceptable; ☐ not acceptable (see explanation).
10. ☐ The ☐ proposed drawing correction and/or the ☐ proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved, ☐ disapproved (see explanation). However, the Patent and Trademark Office no longer makes drawing changes. It is now applicant's responsibility to ensure that the drawings are corrected. Corrections MUST be effected in accordance with the instructions set forth on the attached letter "INFORMATION ON HOW TO EFFECT DRAWING CHANGES", PTO-1474.
12. ☒ Acknowledgment is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☒ been filed in parent application, serial no. 480,364; filed on 5/11/83.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

PTOL-326 (Rev. 7-82) EXAMINER'S ACTION

Applicant's election with traverse of claims 1-7 (a pharmaceutical composition) in Paper No. 4 is acknowledged. The traversal is on the grounds(s) that the compounds of claims 10-12 should be considered with the composition claims. This has not been found persuasive because the scopes of the compounds in the claims are different. The compounds of the distinct groups are related as combination-subcombination. Note that the composition as claimed does not require the particulars of the subcombination (the compound) as claimed for patentability.

The requirement is still deemed to be proper and is therefore made FINAL.

Claims 8-13 have been withdrawn from consideration as they are directed to the non-elected invention.

Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, as the disclosure is enabling only for claims limited in accordance with the teachings at page 2, lines 1- page 4, line 1; page 12, lines 8-10 and 23-25; page 16, lines 13-15 and the examples set forth. See MPEP 706.03(n) and 706.03(z).

Use of the following claim language is unwarranted by the specification:

"bone reabsorption"

"an alkali metal"

"an organic base"

"a basic aminoacid"

the breadth of the claim language, supra is unwarranted by the limited disclosure set forth in the specification.

Moreover, the lack of relative proportions of ingredients in claims 1, 2, 4 and 6-7 is unwarranted by the specification.

Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Expressions such as "at least one" and "suitable" render the claims indefinite in scope.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless-

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 are rejected under 35 U.S.C. 102 (b) as being anticipated by Blum et al., Francis '700, Francis '211, VanDuzee, Fleisch et al, Schmidt-Dunker, Procter and Gamble (Japanese patent), or Francis '537.

The references teach the claimed diphosphonic acids for use "orally" and "systemically" in the amounts claimed. Note

1. Blum et al., at column 5, lines 5-25

2. Francis '211, at column 3, lines 4-7, and column 20, lines [illegible], 11⊕,

3. Francis '700 at column 9,

4. Van Duzee, column 3, lines 9-5 and column 10, lines 55+; etc...

The claims merely read on an old composition.

Claims 1, 2 and 4 are rejected under 35 U.S.C. 102 (b) as being anticipated by Bentzen et al. '527, Bentzen et al. '364, Bassett et al or Baker.

The references cited supra teach compositions comprising a biphosphonic acid of formula I ~~for~~ the method of administration as set forth in the claims.

Claim 7 is rejected under 35 U.S.C. 102 (b) as being anticipated by Chem. Abst. 96:52503t.

The claim presently reads on the compound per se which is set forth in the abstract.

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

> Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claim 6 is rejected under 35 U.S.C. 103 as being unpatentable over Chem. Abstract 96:52503t.

The reference specifically teaches the compound of claim 7 which differs from the one claimed merely in its being one methylene group lacking in the straight alkyl chain. To alter the phosphonylation by using $H_2N(CH_2)4$ CO_2H instead of $H_2N(CH_2)3$ CO_2H would result in the compound herein and would be obvious in the absence of a contrary showing. The compound claimed is merely a homolog of the prior art teaching.

Henze 85 USPQ 261.

Chem. Abst. 100:175062g, Russell et al., Chem Abst. 88:170246u, Francis (Calc. Tiss. Res.), Netherlands 7,308,017, Flora et al. '582, Flora et al, '214, Flora et al. '059, Flora et al '212, Triebwasser, Smith et al. and Rosini have been cited to show the state of the art.

Abramson:ce

A/C 703-557-3920

5-14-85

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SUPERVISORY PATENT EXAMINER
ART UNIT 125